

**§ 21.81 Formula No. 46.**

(a) *Formula.* To every 100 gallons of alcohol add:

Twenty-five fluid ounces of phenol, U.S.P., and 4 fluid ounces of methyl salicylate, N.F.

(b) *Authorized uses.* (1) As a solvent:

220. An antiseptic, sterilizing, and bathing solution having restricted use.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

(c) *Conditions governing use.* This formula may be used only by institutions and organizations which are of a semipublic character and engaged in charitable work.

### Subpart E—Specifications for Denaturants

**§ 21.91 General.**

Denaturants prescribed in this part shall comply with the specifications set forth in this subpart. However, in order to meet requirements of national defense or for other valid reasons, the Director may, pursuant to written application filed by the denaturer, authorize variations from such specifications or authorize the use of substitute denaturants if such variation or substitution will not jeopardize the revenue. Each such application shall identify the applicant by name, address, and permit number; state the number of each formula of specially denatured alcohol involved; explain why the use of the substitute denaturant, or the variation from specifications, as the case may be, is necessary; and include, as applicable, either the identity of the approved denaturant for which substitution is desired and the identity of the substitute denaturant (including the name of the manufacturer) or the identity of the prescribed specifications and the proposed variation from those specifications. The application shall be accompanied by an 8-ounce sample of the proposed denaturing material for analysis.

**§ 21.92 Denaturants listed as U.S.P. or N.F.**

Denaturing materials and products listed in this part as “U.S.P.” or

“N.F.” shall meet the specifications set forth in the current United States Pharmacopoeia or National Formulary, or the latest volume of these publications in which the denaturants appeared as official preparations.

**§ 21.93 Acetaldehyde.**

(a) *Aldehyde content (as acetaldehyde).* Not less than 95.0 percent by weight.

(b) *Color.* Colorless.

(c) *Odor.* Characteristic pungent, fruity odor.

(d) *Specific gravity at 15.56 °/15.56 °C.* Not less than 0.7800.

**§ 21.94 Acetaldol.**

(a) *Purity.* Not less than 90 percent by weight acetaldol as determined by the following method:

Dissolve 15 grams of the acetaldol in distilled water and dilute to 1 liter in a volumetric flask. Transfer 5 ml of this solution to a 250 ml glass-stoppered flask containing 25 ml distilled water. Add 25 ml of a freshly prepared 1 percent sodium bisulfite solution. Prepare a blank omitting the acetaldol solution. Place the flasks in a dark place away from excessive heat or cold and allow to stand six hours. Remove flasks and titrate free bisulfite with 0.1 N iodine solution using starch indicator.

Percent acetaldol by weight =  $(\text{ml blank} - \text{ml test}) \times 200 \times 0.44 / \text{weight of sample}$

Titration in excess of 100 percent may be obtained if the sample contains appreciable amounts of acetaldehyde.

(b) *Specific gravity at 20 °C.* 1.098 to 1.105.

**§ 21.95 Ammonia, aqueous.**

(a) *Alkalinity.* Strongly alkaline to litmus.

(b) *Ammonia content.* 27 to 30 percent by weight. Accurately weigh a glass-stoppered flask containing 25 ml of water, add about 2 ml of the sample, stopper, and weigh again. Add methyl red indicator, and titrate with 1 N sulfuric acid. Each ml of 1 N sulfuric acid is equivalent to 17.03 mg of  $\text{NH}_3$ .

(c) *Color.* Colorless liquid.

(d) *Non-volatile residue.* 2 mg maximum. Dilute a portion of the sample with 1½ times its volume of distilled water. Evaporate 10 ml of this product to dryness in a tared platinum or porcelain dish. Dry residue at 105 °C. for 1 hour, cool and weigh.